UNITED STATE DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

MELANIE ROBERTS, Plaintiff, vs. COOK INCORPORATED, COOK MEDICAL, LLC, WILLIAM COOK EUROPE APS, Defendants,	)	Case No. 3:21-cv-12 **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Melanie Roberts, by and through the undersigned attorneys, hereby sues defendants Cook Incorporated, Cook Medical, LLC, William Cook Europe APS, (collectively, "Cook" and/or the "Defendants") and allege as follows:

1. This is an action for damages relating to the Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion and/or distribution of its unsafe medical device known as the Cook Celect Vena Cava Filter (hereinafter "Cook IVC Filter" or "Cook's IVC Filter").

2. Cook IVC Filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including: tilting, perforation, fracture, breakage and migration.

3. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with its devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of its IVC Filters.

4. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as safe medical devices when in fact Cook had reason to know, and/or did know, that its IVC Filters were not safe for its intended purposes, and that its IVC Filters caused serious injury and death.

5. At all times relevant to this action, Cook is and was liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

PARTIES

6. Plaintiff Melanie Roberts ("Plaintiff") is currently a resident of the City of Dallas Falls, County of Barron, and is a citizen of the State of Wisconsin. Plaintiff was implanted with a Cook Celect Vena Cava Filter on October 6, 2008 at EU Eau Claire Hospital in the City of Eau Claire, County of Eau Claire, State of Wisconsin.

7. Defendant Cook Incorporated (Cook Group, Inc.) is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Defendant Cook Incorporated (Cook Group, Inc.) regularly conducts business in the state of Wisconsin, and is authorized to do so. Defendant Cook Incorporated (Cook Group, Inc.) may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

8. Defendant Cook Incorporated (Cook Group, Inc.) is the parent company of Defendant Cook Medical LLC and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Incorporated (Cook Group, Inc.) regularly conducts business in the state of Wisconsin and is

authorized to do so. Defendant Cook Medical, LLC may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

9. Defendant William Cook Europe APS is based in Bjaeverskov, Denmark and regularly conducts business in the state of Wisconsin, and is authorized to do so. Defendant William Cook Europe APS may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

10. At all times alleged herein, the Defendants include any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

JURISDICTION & VENUE

11. This Court has subject matter jurisdiction under 28 U.S.C. § 1332 because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), excluding interest and costs and there is complete diversity of citizenship between Plaintiff and Defendant.

12. At all times relevant, Cook was engaged in the business of researching, designing, testing, developing, manufacturing, packaging, labeling, marketing, advertising, distributing, promoting, warranting, and selling in interstate commerce, its IVC Filters either directly or indirectly through third parties or related entities in the state of Wisconsin.

13. The Defendants are subject to *in personam* jurisdiction in Wisconsin because of the activity conducted therein. Defendants' activities in Wisconsin include: marketing, advertising, promoting, distributing, and receiving substantial compensation and profits from sales and other

acts that caused or contributed to the harm giving rise to this action. Defendants also made or caused to be made material omissions and misrepresentations and breaches of warranties in the state of Wisconsin. Further, Defendants are present and doing business within this state and have continuous and systematic contacts in every state in the United States of America, including the state of Wisconsin.

14. For purposes of remand and trial, venue is proper pursuant to 28 U.S.C. §1391 in the federal judicial district of Wisconsin.

15. A substantial amount of activity giving rise to the claims occurred in this District. Therefore, venue is proper in this jurisdiction under 28 U.S.C. §1391.

FACTUAL BACKGROUND AND GENERAL ALLEGATIONS

16. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology, and surgical products throughout the United States and around the world. Cook's products at issue in this matter include the Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook Celect Vena Cava Filter, and the Cook Celect Platinum (collectively referred to herein as "Cook Filters") all of which are used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

17. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' product**s** are introduced via a coaxial introducer sheath system.

18. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or its components under Section 510(k) of the Medical Device Amendment.

19. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

20. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

21. An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

22. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach

the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters, is designed to prevent thromboembolic events.

23. The Cook Filters are retrievable filters.

24. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

25. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

26. At all times relevant hereto, the Cook Filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew its Cook Filters were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

27. A retrospective review of all Cook Gunther Tulip Filters and Cook Celect filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept 4, 2008 Technical Note).

28. A retrospective review of 115 patients who underwent Cook Celect IVC filter

insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to hook endothelialization continues to be an issue with this filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

29. In a review of clinical data related to 73 patients who had Celect IVC filter implanted between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

30. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. The authors concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

31. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip and Celect IVC filters and all titled filters also demonstrated vena caval perforation.

Defendants knew or should have known that their IVC filters were more likely than not tilt and to perforate.

32. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients and/or Plaintiff that its Cook Filters were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true**.**

33. At all times relevant hereto, the Defendants continued to promote the Cook Filters as safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

34. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

35. The Cook Filters are constructed of conichrome.

36. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

37. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

38. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

39. The Cook Filters were designed, manufactured, distributed, sold and/or supplied

by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

40. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

41. Plaintiff brings this case for serious injuries suffered as a result of a surgically implanted medical device known as Cook Celect Vena Cava Filter that was implanted on October 6, 2008 at EU Eau Claire Hospital in Eau Claire, Wisconsin, causing serious and ongoing physical, emotional and economic damages

42. Specifically, the Cook IVC Filter has a total of 11 prongs perforating Plaintiff's IVC at a maximum distance of 8.16 mm including prongs perforating both the aorta and duodenum and the filter is tilted 0.52 degree tilt left-to-right, 5.69 degree tilt posterior-to-anterior.

43. Plaintiff has incurred significant medical expenses and have endured extreme pain and suffering, loss of enjoyment of life, disability, and other losses. Plaintiff may require ongoing medical care as well.

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

44. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

45. Cook IVC Filters were defective and unreasonably dangerous when they left the

possession of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

46. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of its IVC Filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

47. At all times relevant hereto, the Cook IVC Filters were dangerous and presented a substantial danger to patients who were implanted with the Cook IVC Filters, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook IVC Filters posed to patients, because their use was specifically promoted to improve health of such patients.

48. Had adequate warnings and instructions been provided, Plaintiff would not have been implanted with Cook IVC Filters, and would not have been at risk of the harmful injuries described herein. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and their medical providers as described herein. Neither Plaintiff, nor Plaintiff' physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cook's IVC Filters.

49. Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Cook IVC Filters.

50. Plaintiff, individually and through their implanting physicians, reasonably relied

upon the skill, superior knowledge and judgment of the Defendants.

51. Defendants had a continuing duty to warn Plaintiff and their physicians of the dangers associated with the subject products.

52. Safer alternatives were available that were effective and without risks posed by Cooks' IVC Filters.

53. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost the ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills, both past and future, related to care because of the Cook IVC Filters' defects.

54. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

55. **WHEREFORE,** Plaintiff, demands judgment against the Cook Defendants and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

56. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

57. Defendants have a duty to provide adequate warnings and instructions for their

products including their IVC Filters, to use reasonable care to design a product that is not unreasonably dangerous to users.

58. At all times relevant to this action, Defendants designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted, and sold their IVC Filters, placing the devices into the stream of commerce.

59. At all times relevant to this action, Cook's IVC Filters were designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a condition that was defective and unreasonably dangerous to consumers, including Plaintiff.

60. Cook IVC Filters are defective in their design and/or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

61. Cook IVC Filters were expected to reach, and did reach, users and/or consumers including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which they were manufactured and sold.

62. Physicians implanted as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by the Defendants. Plaintiff received and utilized Cook IVC Filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by the Defendants.

63. Cook IVC Filters were and are unreasonably dangerous in that, as designed, failed to perform safely when used by ordinary consumers, including Plaintiff, including when the filters were used as intended and in a reasonably foreseeable manner.

64. Cook IVC Filters were and are unreasonably dangerous and defective in design

or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and other serious injury which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative designs for the like products.

65. Cook IVC Filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

66. Cook IVC Filters, as manufactured and supplied, were defective due to inadequate warnings, and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

67. Cook IVC Filters, as manufactured and supplied, were defective due to its no longer being substantially equivalent to its predicate device with regard to safety and effectiveness.

68. Cook IVC Filters as manufactured and supplied by the Defendants are and were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its IVC Filters, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Defendants were directly marketing and advertising; and further, Defendants continued to affirmatively promote their IVC Filters as safe and effective and as safe and effective as their predicate device.

69. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost the ability to live a normal life, and will continue to be so diminished into

the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the IVC filter's defect.

70. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

71. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III: NEGLIGENCE

72. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

73. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including its Cook IVC Filters.

74. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving their IVC Filters.

75. At the time of manufacture and sale of the Cook IVC Filters, the Cook Defendants knew or reasonably should have known that the Cook IVC Filters:

a. were designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. were designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid;

c. were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. were designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena caval wall.

76. Despite the aforementioned duty on the part of the Cook Defendants, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook IVC Filters, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

77. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost the ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook IVC Filters' defects.

78. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

79. **WHEREFORE,** Plaintiff, demands judgment against the Cook Defendants and

seeks damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT IV: NEGLIGENCE PER SE
(Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

80. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

81. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Cook IVC Filters.

82. By reason of its conduct as alleged herein, Cook violated provisions of statutes and regulations, including but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331 and 352, by misbranding its Cook IVC Filters;

b. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 in making statements and/or representations via word, design, device or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook IVC Filters to which the labeling and advertising relates;

c. Defendants violated the 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Cook IVC Filters;

d. Defendants violated the 21 C.F.R. §801 in mislabeling its Cook IVF Filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Cook IVC Filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. Defendants violated the 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

f. Defendants violated the 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when its Cook IVC Filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and

g. Defendants violated the 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions,

83. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT V: BREACH OF EXPRESS WARRANTY

84. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

85. At all times to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cook IVC Filters).

86. At the time and place of sale, distribution and supply of the Cook IVC Filters to Plaintiff (and to other consumer and the medical community), the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC Filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

87. At the time of Plaintiff's purchase from Defendants, the Cook IVC Filters were

not in a merchantable condition and Defendants breached their expressed warranties, in that the filters:

a. were designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. were designed in such a manner so as to result in a unreasonably high incident of injury to the organs of its purchaser; and

c. were manufactured in such a manner so that the exterior surface of the Cook Filters were inadequately, improperly and inappropriately designed causing the device to weaken and fail.

88. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost the ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the IVC filters' defect.

89. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their breach express warranty.

90. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT VI: BREACH OF IMPLIED WARRANTY

91. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

92. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold its IVC Filters.

93. At all relevant times, the Defendants intended its IVC Filters be used in the manner that Plaintiff in fact used them.

94. Defendants impliedly warranted their IVC Filters to be of merchantable quality, safe and fit for the use for which the Defendants intended them and for which Plaintiff in fact used them.

95. Defendants breached their implied warranties as follows:

a. Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Cook IVC Filters would cause harm;

b. Defendants manufactured and/or sold their Cook IVC Filters and said filters did not conform to representations made by the Defendants when they left the Defendants' control;

c. Defendants manufactured and/or sold their Cook IVC Filters which were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Filters' design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Defendants' control; and

d. Defendants manufactured and/or sold their Cook IVC Filters when they deviated in a material way from the design specifications, formulas or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the products left the Defendants' control.

96. Further, Defendants' marketing of their Cook IVC Filters was false and/or misleading.

97. Plaintiff, through their attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

98. Defendants' filters were unfit and unsafe for use by users as they posed an

unreasonable and extreme risk of injury to persons using said products, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

99. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

100. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost the ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the IVC filters' defects.

101. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of its breaches of implied warranty.

102. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT VII: VIOLATIONS OF THE WISCONSIN CONSUMER ACT

103. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

104. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Cook's IVC Filters to Plaintiff.

105. Defendants engaged in unfair, unconscionable, deceptive, fraudulent, and

misleading acts or practices in violation of all states' consumer protection laws, identified below.

106. Through its false, untrue, and misleading promotion of Cook's IVC Filters, Defendants induced Plaintiff to purchase and/or pay for the purchase of Cook's IVC Filters.

107. Defendants misrepresented the alleged benefits and characteristics of Cook's IVC Filters; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Cook's IVC Filters; misrepresented the quality and efficacy of Cook's IVC Filters as compared to much lower-cost alternatives; misrepresented and advertised that Cook's IVC Filters were of a particular standard, quality, or grade that they were not; misrepresented Cook's IVC Filters in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have opted for an alternative IVC Filter or method of preventing pulmonary emboli.

108. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendants' conduct misled, deceived, and damaged Plaintiff, and Defendants' fraudulent, misleading, and deceptive conduct was perpetrated with an intent that Plaintiff relies on said conduct by purchasing and/or paying for purchases of Cook's IVC Filters. Moreover, Defendants knowingly took advantage of Plaintiff, who was reasonably unable to protect their interests due to ignorance of the harmful adverse effects of Cook's IVC Filters.

109. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiff and offends the public conscience.

110. Plaintiff purchased Cook's IVC Filters primarily for personal, family, or household purposes.

111. As a result of Defendants' violative conduct in each of the Plaintiff's respective

states, Plaintiff purchased and/or paid for purchases of Cook IVC Filters that were not made for resale.

112. Defendants engaged in unfair competition or deceptive acts or practices in violation of Wisconsin Statutes Chapters 421–27.

113. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT VIII: PUNITIVE DAMAGES

114. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

115. At all times material hereto, Defendants knew or should have known that their Cook IVC Filters were inherently dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

116. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of their Cook IVC Filters.

117. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of their Cook IVC Filters. The Defendants' conduct was willful, wanton, and undertaken with a conscious indifference to the consequences that consumers of their product faced, including Plaintiff.

118. At all times material hereto, Defendants knew and recklessly disregarded the fact that their Cook IVC Filters have an unreasonably high rate of tilt, fracture, migration and/or

perforation.

119. Notwithstanding the foregoing, Defendants continued to market their Cook IVC Filters aggressively to consumers, including Plaintiff, without disclosing the aforesaid side effects.

120. Defendants knew of their IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell their Filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by Cook's IVC Filters.

121. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable them to weigh the true risks of using Cook IVC Filters against their benefits.

122. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for their safety and rights, consumers including Plaintiff, have suffered and will continue to suffer severe and permanent physical and emotional injuries, as described with particularity, above. Plaintiff has endured and will continue to endure pain, suffering, and loss of enjoyment of life; and has suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment and lost wages.

123. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the safety and rights of consumers including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

TOLLING OF THE LIMITATIONS PERIOD

124. Plaintiff repeats, re-alleges, and incorporates herein by reference, all of the preceding allegations as though set forth in full. Plaintiff pleads this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of Wisconsin.

125. Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with Cook's IVC Filters.

126. As a result of Defendants' actions, Plaintiff and their prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

127. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with a Cook IVC Filter and the harm Plaintiff suffered as a result.

128. Additionally, the accrual and running of any applicable statute of limitations have been tolled by reason of Defendants' fraudulent concealment.

129. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

130. Additionally, the limitations period ought to be tolled under principles of equitable tolling.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff demands judgment against the Cook Defendants as follows:

A. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; past and future lost wages and loss of earning capacity; funeral and burial expenses; and consequential damages;

B. Punitive damages in an amount sufficient to punish Defendants and set an example;

C. Disgorgement of profits;

D. Restitution;

E. Costs and fees of this action, including reasonable attorney's fees;

F. Prejudgment interest and all other interest recoverable; and

G. Such other additional and further relief as Plaintiff may be entitled to in law or in equity according to the claims pled herein.

DEMAND FOR JURY TRIAL

The Plaintiff respectfully requests trial by jury in the above case as to all issues.

Dated: January 8, 2021

Respectfully submitted,

/s/ Jonathan R. Mencel
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